



U.S. Military Smallpox Vaccination Program

Science – Care – Quality – Confidence

Armed Forces Epidemiological Board
17 September 2003

COL John D. Grabenstein, RPh, PhD
U.S. Army Medical Command



DoD Smallpox Vaccination Policy

- Announced by President Bush, 13 Dec 02.
 - Vaccinate troops before an attack to ensure they are personally protected and can continue their missions.
- Stages:
 - Stage 1a: Smallpox Epidemic Response Teams (SERTs).
 - 2,000 to 5,000 people, began mid-Dec 02
 - Stage 1b: Medical Teams for Hospitals & Large Clinics.
 - 10,000 to 25,000 people, began early Jan 03
 - Stage 2: Mission-Critical Forces, especially CENTCOM.
 - About 500,000 troops, began early Jan 03

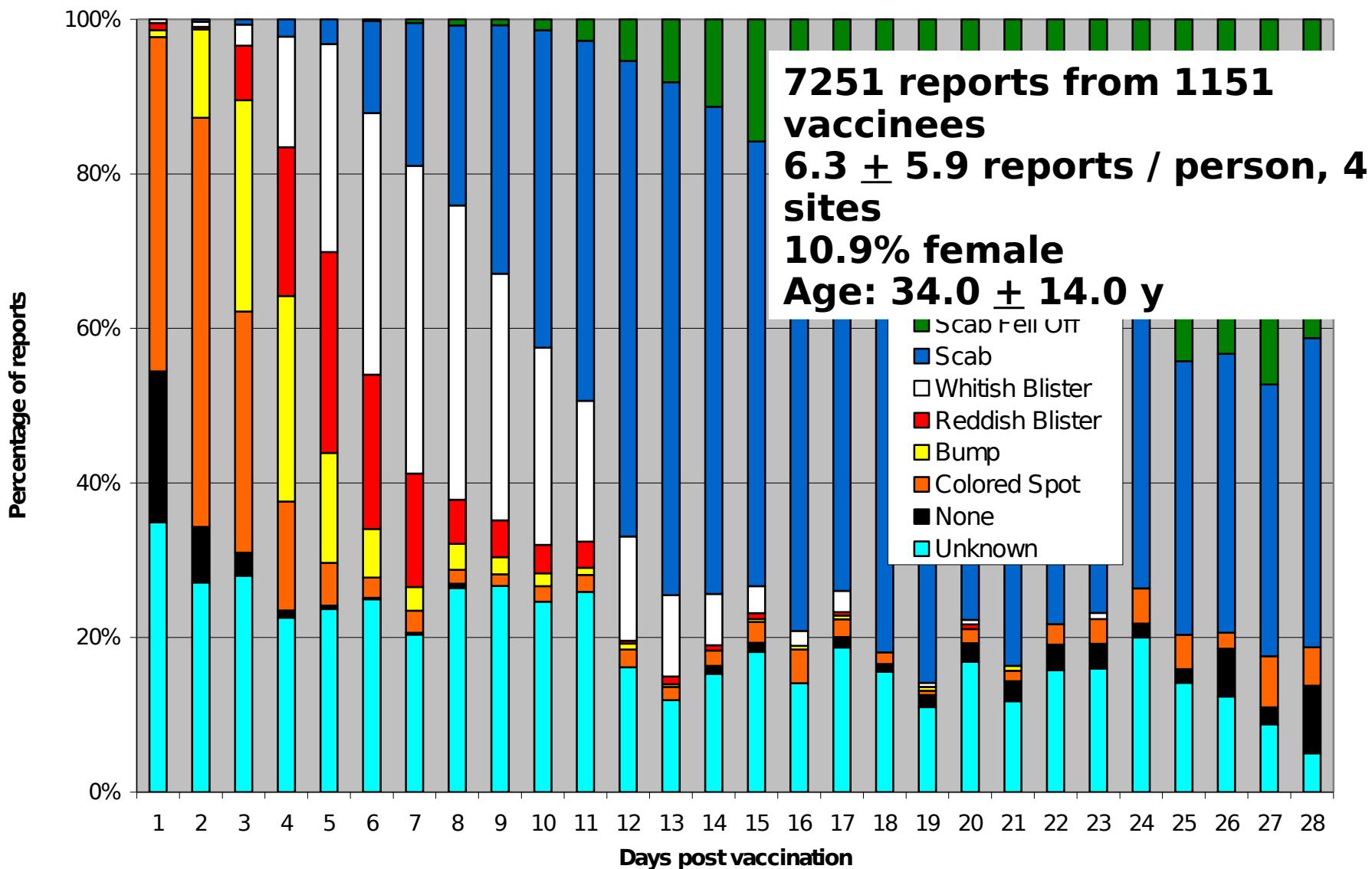


DoD Smallpox Vaccination Program as of 11 Sep 03

- Response teams, hospital workers, operational forces
Screened: 565,000 Vaccinated: 492,716
 - Primary: 71% Male: 87%
 - Exemption rates vary by location:
 - Personal: 5% to 10%
 - Personal + household: 20% to 30%
 - Take (3 sites):
 - Primary, 3 jabs: 96% Revaccination, 15 jabs: 96%
 - Adverse Events: Expected temporary symptoms.
 - Sick leave: Average: 1.5 d
 - Hospital staff: 3% Primary--5.5% Revax—1.5%
 - Deployed troops: 0.5%



Vaccinee description of vaccination sites - percentage of reports submitted





Symptoms After Smallpox Vaccination

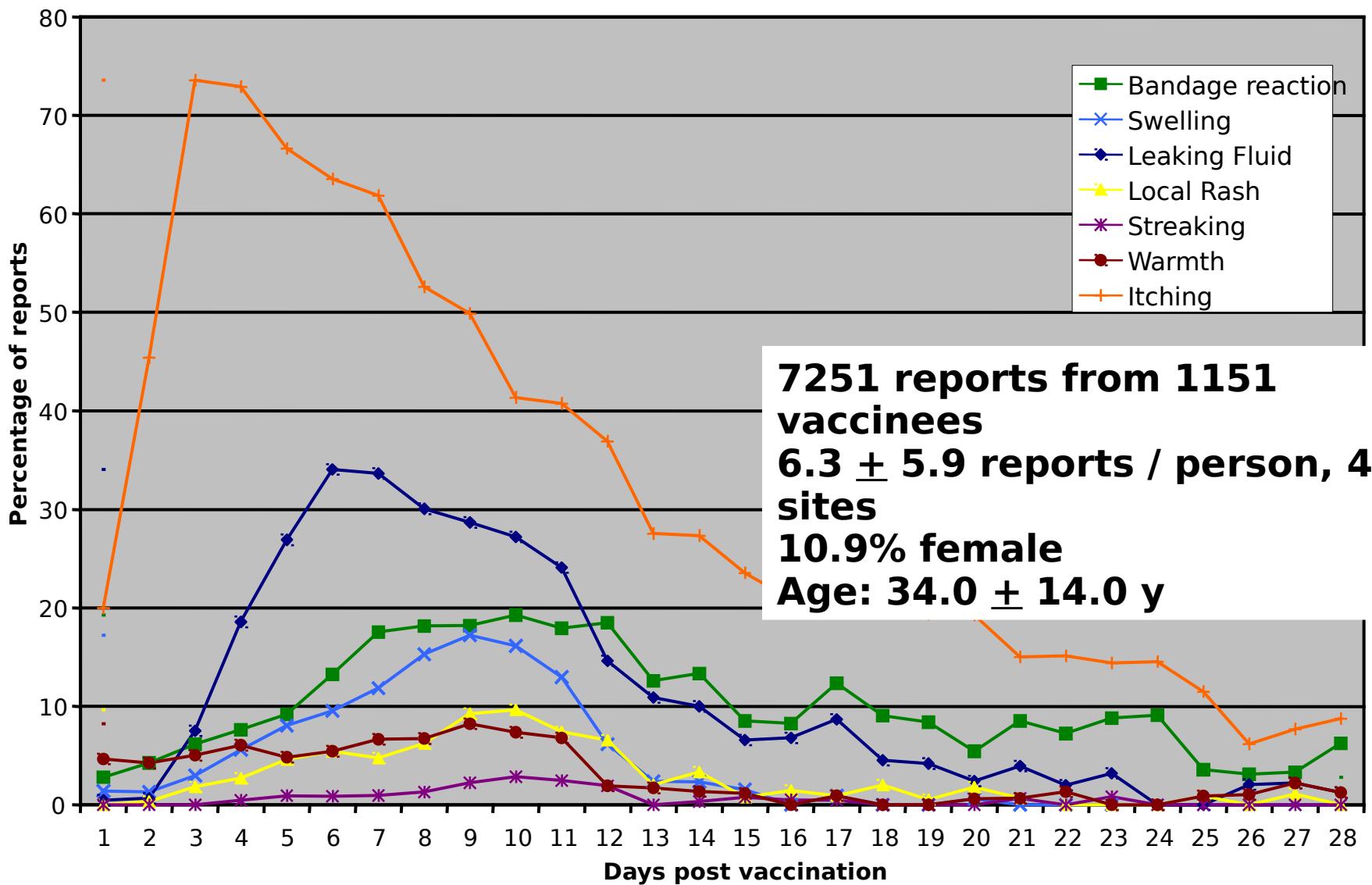
Day 6-8, "Take Check," symptoms since vaccination, n = 526, Jan-Feb 2003

- Local itching 60% Muscle ache 21%
- Feeling lousy 20% Lymph nodes swell 14%
- Headache 18% Bandage reaction 7.4%
- Itchy all over 5.5% Fever (subjective) 5.3%
- Local rash 5.3% Body rash 1.1%
- Eye infection 0.0%

- Restricted activity 1.3% Took medication 17%
- Outpatient visit 0.8% Limited duty 0.0%
- Missed work 0.2% Hospitalized
- 0.0%

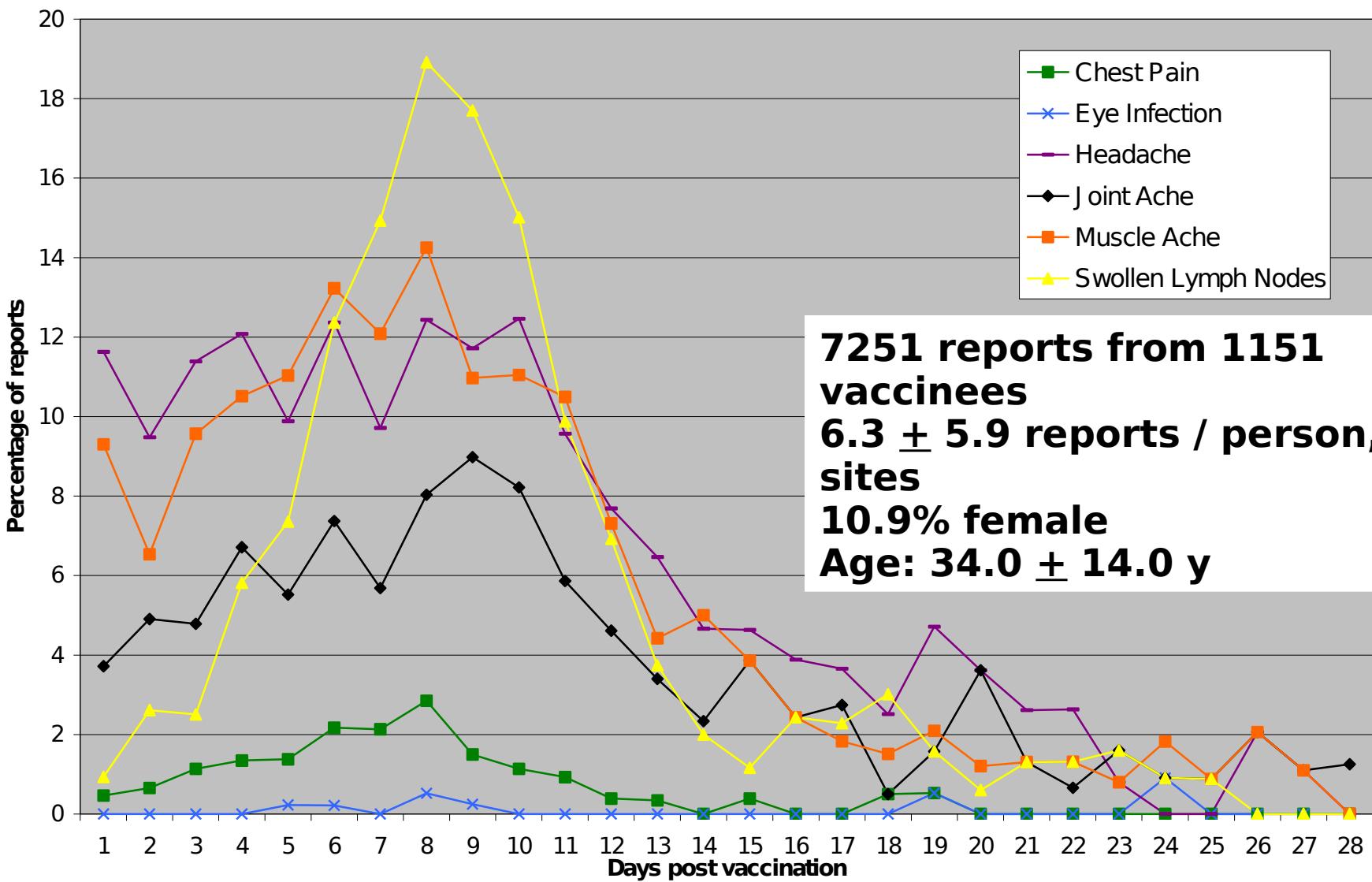


Percentage of reports describing local symptoms





Percentage of reports describing systemic symptoms





Screening Before Smallpox Vaccination

11 Sep 03 n = 4,903

DoD INITIAL MEDICAL NOTES	Self	Contact
No restriction	3,858	3,078
Pregnancy	30	136
Skin condition	149	208
Relevant allergy	43	
Other / unsure	100	59
Immune suppression	32	48
Heart condition	n/a	n/a
Primary Vaccinees	3,268	
Revaccinees	1,416	
Deferred pending consult, lab	43	
Deferred, temporary contraindication	363	
Contraindicated unless exposed	92	
Vaccination not given, other	24	

Further analyses planned



DoD Smallpox Vaccination Program as of 11 Sep 03

- Noteworthy Events among 490,219 Vaccinees:
 - Encephalitis— 1—recovered
 - Generalized vaccinia— 33, all mild, all recovered
 - Inadvertent infection—Skin: Self—48, Contact—27
 - Inadvertent infection—Eye: Self—11, Contact— 2
 - Contact transfer:
 - Family—14, intimate contact—7, friend—8, patient—0
 - Vaccinia Immune Globulin (VIG) treatments: Burn-1, eye-1
 - Myo-pericarditis: Suspect—0, probable—54, confirmed—2
 - Eczema vaccinatum: zero Progressive vaccinia: zero
 - Deaths: Attributed to vaccine: 0 Not attributed to vaccine: 3



DoD Smallpox Vaccination Program Myo-pericarditis cases, as of 11 Sep 03

- People vaccinated: 492,716
- Myo-pericarditis: Suspect—0, probable—54, confirmed—2
- Of the first 18 cases: *JAMA* 2003;289:3283-89
 - Onset interval: 7 to 19 d.
 - Male: 18/18 Age: 21 to 33 years
 - Primary vaccination: 18/18 Present with chest pain: 18/18
 - Enzymes elevated: 18/18 ECG—ST changes: 16/18
 - Echo—abnormal: 10/18 Recover: 18/18, following-up
 - Relative risk: 3.6 for a 30-day interval (95% CI: 3.3, 4.1)
- Conclusion: Smallpox vaccination appears to increase risk of myo-pericarditis among adult male primary vaccinees.



Myo-pericarditis Case Follow-Up

- Thru 31 Jul 03
- 52 males, 1 female, aged 21 to 43 years
- confirmed (1 male; 1 female); probable (51 males)
- Primary vaccination: 50/53
- Incidence: 15.36/100,000 primary vaccinees,
 - Relative risk = 7.1 (6.6, 8.1)
- 35 (67%) available for comprehensive follow-up, 8 \pm 6 w.
 - 28 (80%) report complete clinical recoveries
 - 22 normal resting echocardiography
 - 13 normal stress exercise testing
 - 2 (6%) persistent non-specific resting ECG changes
 - 7 (20%) persistent subjective symptoms (eg, chest pain).



Early Pregnancy Outcomes Among Women Exposed to Smallpox Vaccine in Pregnancy

National Smallpox Vaccine in Pregnancy Registry

Margaret Ryan, DOD Birth and Infant Health Registry

Jane Seward, Kristin Kenyan, Joseph Mulinare, CDC, and others DOD and CDC

149 military women registered with vaccinia exposure.

- Age: mean 23 y (range: 18-41y). First pregnancy for 63%.
- 40% vaccinated before conception.
- 28% vaccinated after conception, but before pregnancy test could be +
- 32% vaccinated after 4 weeks gestational age

Among 149 pregnancies:

- 129 progressed to 2nd trimester
- 13 had spontaneous abortion (miscarriages)
- 5 had elective abortions
- 2 had ectopic pregnancies

Miscarriage rate: Observed: 8.7% to 9.5%. Expected: 9% to 12%.

Ectopic rate:

Observed: 1.3%.

Expected: 1%

to 2%.



Contact Transfer of Vaccinia Virus as of 11 Sep 03

- Dec 02 -- Sep 03, 492,716 people vaccinated
- Skin—27, Eye— 2
- Family—14, adult intimate contacts—7, 'sport' partners—6, other friends—2, patient—0
- CO (4), TX (4), NC (4), AK (2), CA (2), CT (1), KS (1), LA (1), OH (1), WA (1), WV (1), overseas (7).
- Viral culture and/or PCR positive: 19 cases; others not tested
- Incidence rate: 5.9 per 100,000 vaccinees overall
 - or 8.4 per 100,000 primary vaccinees.
 - Historical rate: 2 to 6 per 100,000 primary vaccinations.
 - Today: Less immunity among general population.
- Conclusion: Principal risk is to people who share the same bed.
 - Second: Failure to use bandages according to instructions.



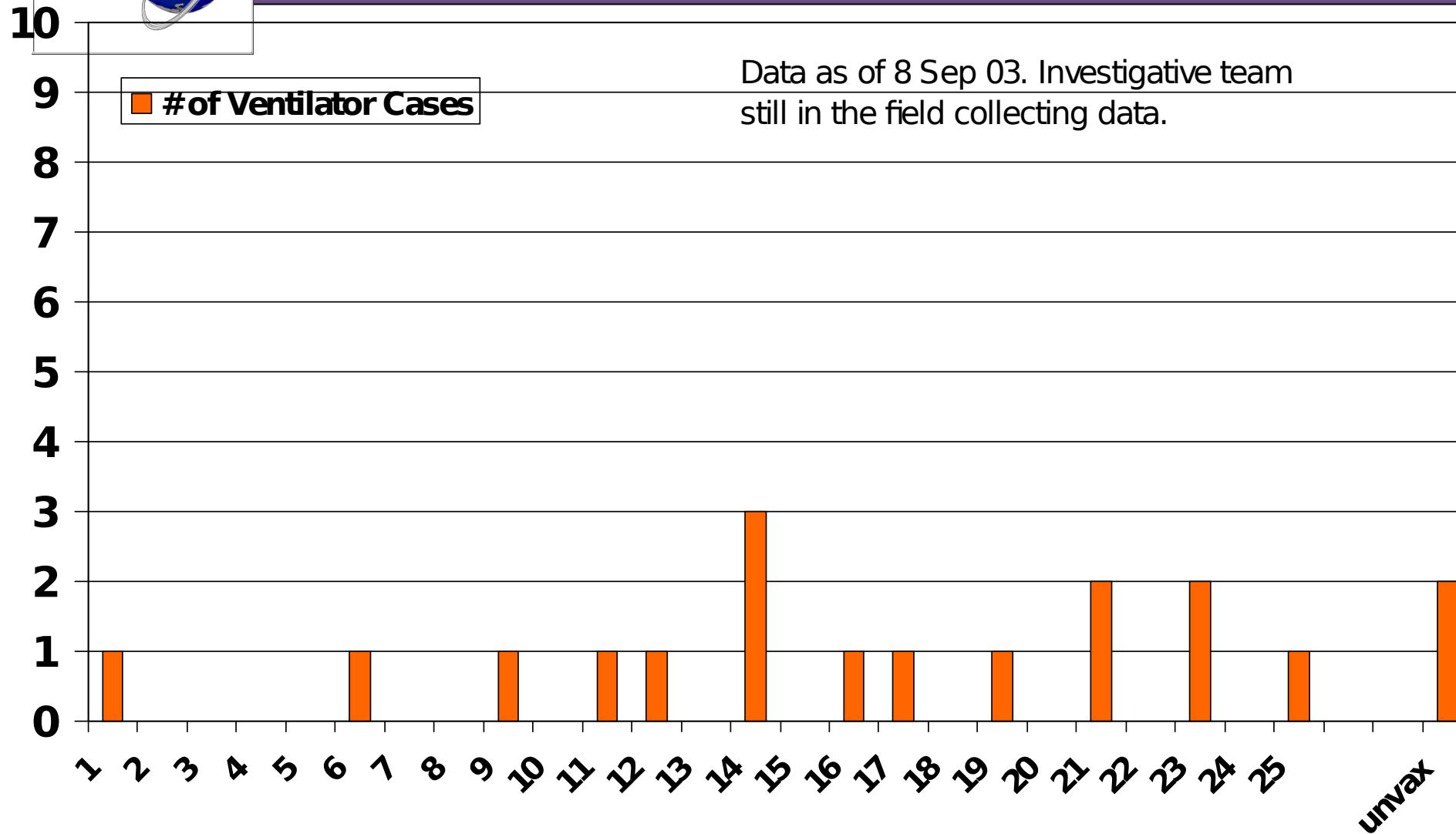
Military Vaccination vis-à-vis Pneumonia

	Rate of hospitalization per 10,000 people per year	95% Confidence Interval
U.S. Army active-duty personnel, worldwide, 2002	10.3	9.3 to 11.1
U.S. Army active-duty personnel, excluding basic training posts, 2002	5.0	4.3 to 5.7
U.S. Army, anthrax- vaccinated only, Dec 02 to Jul 03	2.4	0.8 to 5.5
U.S. Army, smallpox- vaccinated only, Dec 02 to Jul 03	3.0	0.1 to 16.5
U.S. Army, both anthrax- and smallpox-vaccinated Source: Defense Medical Surveillance System, 5 Sep 03 to 5.2 Dec 02 to Jul 03 Based on ICD-9-CM codes 480 through 487 for pneumonia and influenza.	3.3	1.9 to 5.2

Based on personnel reflected on 3rd PERSCOM deployment roster.



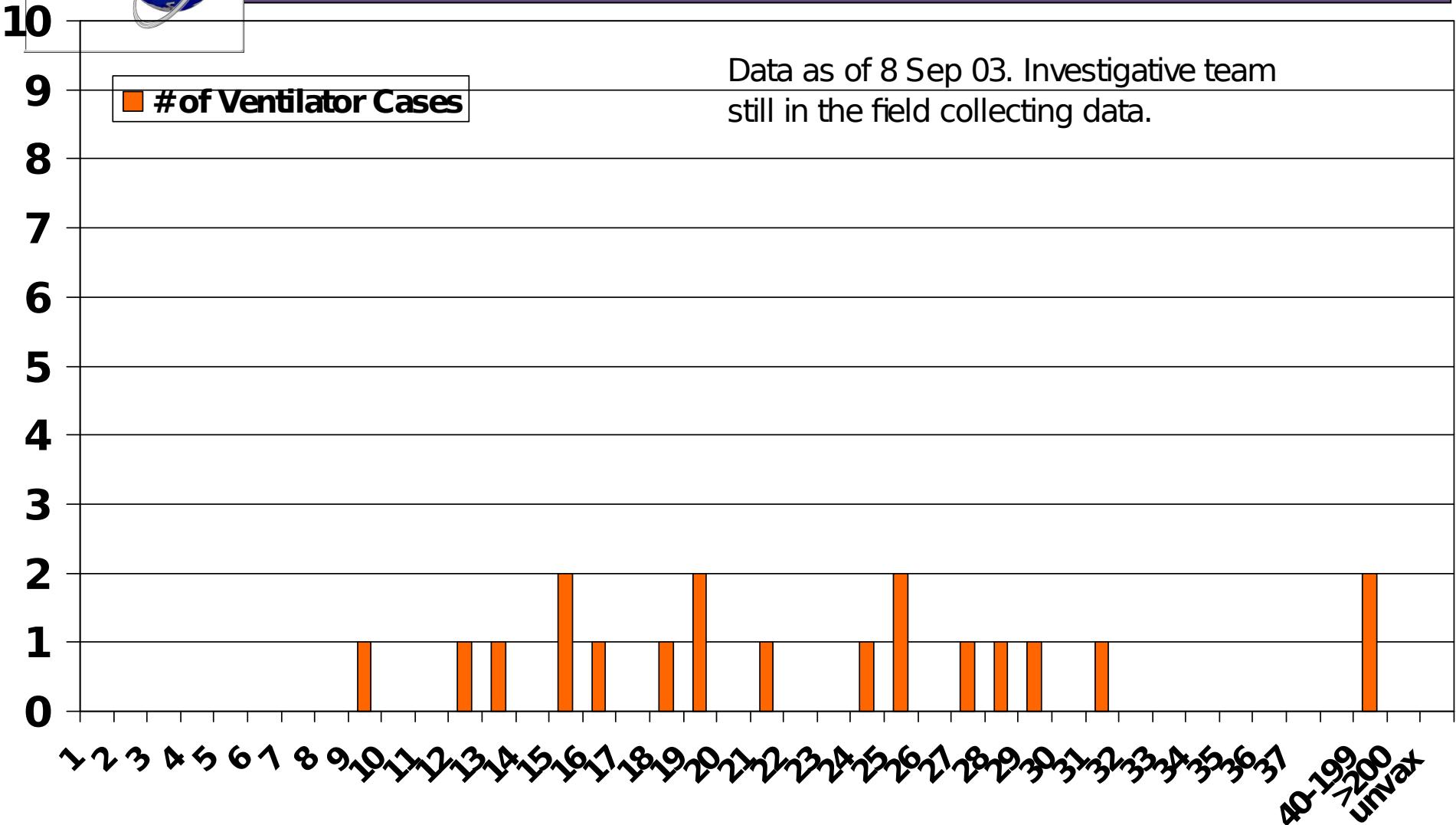
Data as of 8 Sep 03. Investigative team
still in the field collecting data.



**Weeks between smallpox
vaccination and pneumonia
admission**



Data as of 8 Sep 03. Investigative team
still in the field collecting data.



**Weeks between first anthrax
vaccination and pneumonia
admission**



10

9

8

7

6

5

4

3

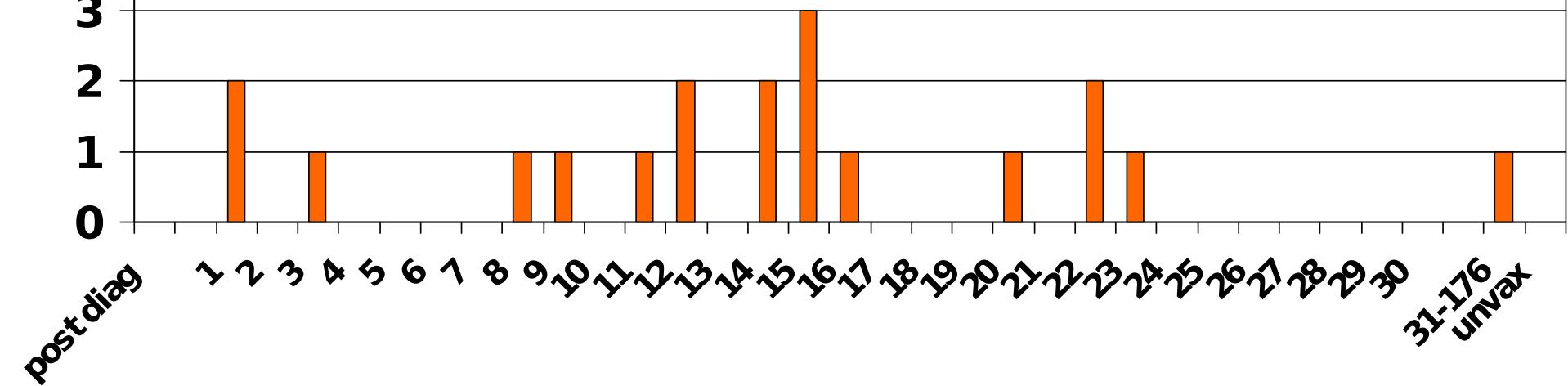
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1

0

of Ventilator Cases

Data as of 8 Sep 03. Investigative team
still in the field collecting data.



**Weeks between most recent anthrax
vaccination and pneumonia admission**



Vaccinia Lessons Learned

- Careful screening reduces adverse events < or = 1960s levels.
 - VIG needed less frequently than expected.
- Education and screening are rate-limiting steps.
- 3 or 15 jabs yield high “take” rates.
- Clinicians ‘alarmed’ by first (maculopapular) rashes they saw in vaccinees; lessened with experience.
- Secondary spread of vaccinia: greatest risk is to bed partners.
- Myo-pericarditis is greater risk than anticipated, principally male, primary vaccinees in DoD’s experience.



Response to AFEB Evaluation of 18 Feb 03

Observation		Response
Uniform implementation of documentation (6.d) (6.l)	Plan - ning	Services responsible for audits. Audits being coordinated with DoDIG.
Analyze short-term follow-up data (6.f) (6.h)	✓	4,903 notes analyzed, 526 symptom survey, Voxiva temporal trends for adverse events.
Studies evaluating effectiveness of health risk-communication program (6.f)	✓	CHPPM report provided; data from all three Services.
Plans for long-term evaluation of chronic and subjective outcomes (6.f)	✓	DMSS database analyses by AMSA. Millennium Cohort Study by NHRC. Flight physicals by USAARL. Disability discharges by USARIEM.
Electronic inpt and outpt med rcds in theater (6.f)	✓	Selected data: GEMS > SAMS. Eventually to be relayed to DMSS. MEDEVAC database ✓.
DoD to encourage participation in pregnancy registry (6.f)	✓	Multiple channels: 28 Feb satellite broadcast, OBs+FPs, MILVAX listserv, Service messages, website, MMWR

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SMALLPOX VACCINATION PROGRAM

[contact us](#)

- Smallpox is contagious, deadly, and would disrupt military missions.
- Smallpox vaccine prevents smallpox and we will use it carefully.
- Preserving the health and safety of our people is our top concern.
- The Defense Department's smallpox vaccination program is part of our national strategy to safeguard Americans against smallpox attack.

MIL VAX

Program

SVP Online Proficiency Training

DoD's Smallpox Vaccination Lessons Learned

MMWR-Vaccinia Adverse Reactions

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Last Updated 01/27/2003